



**DEPARTMENT OF JUSTICE**  
**Drug Enforcement Administration**

**Crosby Pharmacy and Wellness; Decision and Order**

**I. INTRODUCTION**

On October 23, 2021, the Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause (hereinafter, OSC) to Crosby Pharmacy and Wellness (hereinafter, Applicant) of Montgomery, Texas. OSC, at 1. The OSC proposes the denial of Applicant's registration application, Control No. W20008908A (hereinafter, registration application). It alleges that Applicant materially falsified its registration application and that Applicant's registration would be "inconsistent with the public interest, as that term is defined in 21 U.S.C. 823(f)." *Id.*

Specifically, the OSC alleges that, during an onsite visit when Applicant was a registrant, the Government discovered "serious recordkeeping violations," including not maintaining an initial inventory, not maintaining a biennial inventory, and not maintaining accurate records of all controlled substances received and sold. *Id.* at 1-2 (citing 21 CFR 1304.11(b), 1304.11(c), 1304.21(a)). The OSC also alleges that Applicant materially falsified its registration application by answering "no" to the question of whether it had "ever surrendered (for cause) or had a federal controlled substance registration revoked, suspended, restricted, or denied, or is any such action pending." *Id.* at 2.

The OSC notifies Applicant of the right to request a hearing on the allegations or to submit a written statement, while waiving the right to a hearing; the procedures for electing each option; and the consequences for failing to elect either option. *Id.* at 3 (citing 21 CFR 1301.43). The OSC also notifies Applicant of the opportunity to submit a corrective action plan. *Id.* at 3-4 (citing 21 U.S.C. 824(c)(2)(C)).

**II. Adequacy of Service**

In a sworn Declaration dated August 20, 2021 (hereinafter, Declaration), a Diversion Investigator (hereinafter, DI) assigned to the Houston Division Office in Houston, Texas, stated that she “caused a copy of the . . . [OSC] to be sent to . . . [Applicant] at . . . [its] proposed registered address via First Class Mail and Certified Mail.” DI Declaration, at 3. She stated that “[b]oth of these mailings were returned to DEA.” *Id.* The DI also stated that, on November 12, 2020, she “caused a copy of the . . . [OSC] to be emailed” to Applicant at the “email address . . . given to DEA by . . . [Applicant] in . . . [its registration a]pplication.” *Id.* According to the DI’s sworn Declaration, she “did not receive any notification that the message was not delivered.” *Id.*

The Government forwarded its Request for Final Agency Action (hereinafter, RFAA), along with the evidentiary record, to this office on August 24, 2021. In its RFAA, the Government represented that “Applicant did not request a hearing” and requested that I “enter an order denying Applicant’s application.” RFAA, at 1.

Based on the DI’s Declaration, the Government’s written representations, and my review of the record, I find that the Government accomplished service of the OSC on Applicant on or about November 12, 2020. I also find that more than thirty days have now passed since the Government accomplished service of the OSC. Further, based on the Government’s written representations, I find that neither Applicant, nor anyone purporting to represent Applicant, requested a hearing, submitted a written statement while waiving Applicant’s right to a hearing, or submitted a corrective action plan. Accordingly, I find that Applicant has waived the right to a hearing and the right to submit a written statement and corrective action plan. 21

CFR 1301.43(d); 21 U.S.C. 824(c)(2)(C). I, therefore, issue this Decision and Order based on the record submitted by the Government, which constitutes the entire record before me. 21 CFR 1301.43(e).

### **III. FINDINGS OF FACT**

#### **A. Applicant’s Registration History**

I find there is substantial uncontroverted record evidence that Applicant previously held registration No. FC7640623. RFAA Exhibit (hereinafter, RFAAX) 3, at 1. I find there is substantial uncontroverted record evidence that Applicant surrendered that registration for cause by signing a DEA-104, “Surrender for Cause of DEA Certificate of Registration” on January 8, 2020. RFAAX 4, at 1. Further, I find there is substantial uncontroverted record evidence that, on or around January 29, 2020, Applicant submitted the registration application. DI Declaration, at 2; RFAAX 2, at 1-3. I find clear, unequivocal, convincing, and un rebutted record evidence that, on the registration application, Applicant certified that it had never “surrendered (for cause) . . . a federal controlled substance registration.” RFAAX 2, at 1. I find there is substantial uncontroverted record evidence that DEA issued this OSC about the registration application. OSC, at 1; RFAAX 4, at 2.

## **B. Investigation of Applicant**

I find there is substantial uncontroverted record evidence that DI and other DEA employees “conducted an onsite visit” of Applicant on January 8, 2020. DI Declaration, at 1. I find there is substantial uncontroverted record evidence that, during this visit, the DEA team “discovered a number of problems with . . . [Applicant’s controlled-substance-related] recordkeeping.” *Id.* I further find there is substantial uncontroverted record evidence that DI “confronted” a representative of Applicant about “some” of the recordkeeping problems. *Id.* at 2. I find there is substantial uncontroverted record evidence that, “[i]n response,” a representative of Applicant “agreed to surrender” Applicant’s registration and signed a DEA-104 stating that Applicant was “surrender[ing its registration] for cause.” *Id.*; RFAAX 4, at 1. I find there is substantial uncontroverted record evidence that DEA sent Applicant a letter, dated January 24, 2020, “confirming the surrender of . . . [its] registration privileges in Schedules II through V on January 8, 2020,” and stating that, “[c]oncurrent with the surrender,” Applicant is “no longer authorized to order, distribute, possess, dispense, administer, prescribe, or engage in any activities with controlled substances under DEA Registration Number FC7640623.”

RFAAX 7, at 1. I find there is substantial uncontroverted record evidence that DEA directed the January 24, 2020 letter to Applicant at the physical address Applicant submitted in the registration application. RFAAX 7, at 1; RFAAX 2, at 1.

I find there is substantial uncontroverted record evidence that DI continued the investigation of Applicant after its voluntary registration surrender for cause by issuing an administrative subpoena to Applicant's distributor. RFAAX 5, at 1; DI Declaration, at 2. I find there is substantial uncontroverted record evidence that, pursuant to the administrative subpoena, Applicant's distributor provided DI with DEA Form 222s and invoices. DI Declaration, at 2. I find there is substantial uncontroverted record evidence that these distributor documents show that the distributor provided Applicant with more than 18,000 tablets of oxycodone 30 mg, more than 16,000 tablets of hydrocodone/acetaminophen 10/325 mg, more than 13,000 tablets of alprazolam 2 mg, more than 20,000 tablets of carisoprodol 350 mg, and 120 bottles of 473 ml promethazine with codeine. *Id.*; *see also* RFAAX 6. I find there is substantial uncontroverted record evidence that the distributor shipped controlled substances to Applicant. DI Declaration, at 2; RFAAX 6. I find there is substantial uncontroverted record evidence that Applicant did not produce for the DEA team an initial inventory of the controlled substances, "any records of dispensing any controlled substances," and "any controlled substances." DI Declaration, at 1.

### **III. DISCUSSION**

#### **A. The Controlled Substances Act and the Public Interest Factors**

Pursuant to the Controlled Substances Act (hereinafter, CSA), "[t]he Attorney General shall register practitioners . . . to dispense . . . controlled substances . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices." 21 U.S.C. 823(f). The CSA further provides that an application for a practitioner's registration may be denied upon a determination that "the issuance of such registration . . . would be inconsistent with the public interest." *Id.* In making the public interest determination, the CSA requires consideration of the following factors:

- (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.
- (2) The applicant's experience in dispensing . . . controlled substances.
- (3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.
- (4) Compliance with applicable State, Federal, or local laws relating to controlled substances.
- (5) Such other conduct which may threaten the public health and safety.

*Id.*

These factors are considered in the disjunctive. *Robert A. Leslie, M.D.*, 68 FR 15,227, 15,230 (2003). I “may rely on any one or a combination of factors and may give each factor the weight [I] deem[ ] appropriate in determining whether . . . an application for registration [should be] denied.” *Id.* Moreover, while I am required to consider each factor, I “need not make explicit findings as to each one,” and I “can give each factor the weight . . . [I] determine[ ] is appropriate.” *Jones Total Health Care Pharmacy, LLC v. Drug Enf’t Admin.*, 881 F.3d 823, 830 (11th Cir. 2018) (quoting *Akhtar-Zaidi v. Drug Enf’t Admin.*, 841 F.3d 707, 711 (6th Cir. 2016)); *see also MacKay v. Drug Enf’t Admin.*, 664 F.3d 808, 816 (10th Cir. 2011) (quoting *Volkman v. Drug Enf’t Admin.*, 567 F.3d 215, 222 (6th Cir. 2009) (quoting *Hoxie v. Drug Enf’t Admin.*, 419 F.3d 477, 482 (6th Cir. 2005))). In other words, the public interest determination “is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest; what matters is the seriousness of the registrant’s misconduct.” *Peter A. Ahles, M.D.*, 71 FR 50,097, 50,098-99 (2006).

The OSC in this matter, as already discussed, alleges that Applicant’s registration application should be denied because it would be inconsistent with the public interest for Applicant to have a registration and because Applicant’s registration application contains a materially false response to a liability question. OSC, at 1-3; 21 U.S.C. 823(f), 824(a)(1); *supra* section II. A determination that the issuance of a registration “would be inconsistent with the

public interest” is a basis for the denial of a registration application. 21 U.S.C. 823(f). The CSA, however, places the provision addressing the ramification of a material falsification with the bases for revocation or suspension of a registration. 21 U.S.C. 824(a).

Prior Agency decisions have addressed whether it is appropriate to consider a material falsification and other bases for revocation or suspension described in 21 U.S.C. 824(a) when determining whether or not to grant a practitioner registration application.<sup>1</sup> For over forty-five years, and as recently as late last year, Agency decisions have concluded that it is. *See, e.g., Lisa M. Jones, N.P.*, 86 FR 52,196 (2021); *Robert Wayne Locklear*, 86 FR 33,738 (2021) (collecting Agency decisions). These decisions offer multiple bases and analyses for that conclusion. 86 FR at 33,744-45. For example, a prior decision noted that “[t]o hold otherwise would mean that applications would have to be granted [under 21 U.S.C. 823(f)] only to be revoked the next day” under 21 U.S.C. 824(a). *Id.* at 33,744 (quoting *John R. Amato, M.D.*, 40 FR 22,852 (1975)). I reaffirm my decision in *Lisa M. Jones, N.P.* that a basis for revocation or suspension described in a provision of 21 U.S.C. 824(a) may be the basis for the denial of a practitioner registration application.

## **B. Allegation that Applicant Submitted a Materially False Registration Application**

Having read and analyzed all of the record evidence, I find from clear, unequivocal, convincing, and un rebutted record evidence that Applicant surrendered (for cause) its DEA registration on January 8, 2020. *Supra* section II.A, section II.B; RFAAX 4. Having read and analyzed all of the record evidence, I find from clear, unequivocal, convincing, and un rebutted record evidence that Applicant answered “no” to the second liability question in the registration application – whether Applicant “ever surrendered (for cause) . . . a federal controlled substance registration.” *Supra* section II.A. Applicant’s false answer to the second liability question in the registration application implicates two of the public interest factors that the CSA requires me to consider: Applicant’s experience in dispensing controlled substances, and Applicant’s

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<sup>1</sup> A pharmacy is a “practitioner.” 21 U.S.C. § 802(21).

compliance with applicable federal laws relating to controlled substances. 21 U.S.C. 823(f)(2), (4); *Frank Joseph Stirlacci, M.D.*, 85 FR 45,229, 45,234 (2020). As such, Applicant's false response to the second liability question in the registration application was "predictably capable of affecting, *i.e.*, had a natural tendency to affect" my official decision on its registration application. *Frank Joseph Stirlacci, M.D.*, 85 FR at 45,238. Accordingly, I find from clear, unequivocal, convincing, and un rebutted record evidence that the registration application contains a material falsification, an independent basis for the denial of the registration application.

**C. Allegation that Issuing a Registration to Applicant Would Be Inconsistent with the Public Interest**

As already discussed, the OSC includes three allegations that Applicant failed to maintain required "controlled substances records." OSC, at 2. First, the OSC alleges that Applicant "failed to maintain an initial inventory, in violation of 21 CFR 1304.11(b)." *Id.* As already discussed, based on substantial uncontroverted record evidence that the distributor shipped controlled substances to Applicant, I find there is substantial uncontroverted record evidence that Applicant did not produce for the DEA team an initial inventory of the controlled substances, "any records of dispensing any controlled substances," and "any controlled substances." *Supra* section II.B. Accordingly, I find that Applicant violated the CSA by failing to maintain an initial inventory, implicating 21 U.S.C. 823(f)(2) and (4). 21 CFR 1304.11(b).

Second, the OSC alleges that Applicant "failed to maintain a biennial inventory, in violation of 21 CFR 1304.11(c)." OSC, at 2. There is no evidence in the record that supports this allegation. Accordingly, I find that this OSC allegation is not founded.

Third, the OSC alleges that Applicant "failed to maintain accurate records of all controlled substances received and sold, in violation of 21 CFR 1304.21(a)." *Id.* As already discussed, based on substantial uncontroverted record evidence that the distributor shipped controlled substances to Applicant, I find there is substantial uncontroverted record evidence that Applicant did not produce for the DEA team "any records of dispensing any controlled

substances” and “any controlled substances.” *Supra* section II.B. Accordingly, I find that Applicant violated the CSA by failing to maintain accurate records of all controlled substances received and sold, implicating 21 U.S.C. 823(f)(2) and (4). 21 CFR 1304.21(a).

The Government has the burden of proof in this proceeding. 21 CFR 1301.44(d). I carefully considered all of the record evidence relevant to the material falsification allegation, the recordkeeping allegations, and the public interest factors of 21 U.S.C. 823(f)(2) and (4). For the above-stated reasons, I find that the Government met its burden on the OSC’s material falsification allegation and on two of the OSC’s three recordkeeping violation allegations. I further find that Applicant did not submit any evidence, let alone evidence that rebuts the Government’s *prima facie* case, on these founded OSC allegations. Accordingly, I conclude that it would be “inconsistent with the public interest” for me to grant the registration application. 21 U.S.C. 823(f).

#### IV. SANCTION

Where, as here, the Government presented a *prima facie* case that it would be “inconsistent with the public interest” to grant the registration application, and Applicant did not rebut the Government’s *prima facie* case, the “burden of proof shifts” to Applicant “to show why it can be trusted with a registration.” *Jones Total Health Care Pharmacy, LLC v. Drug Enf’t Admin.*, 881 F.3d at 830; *see also Samuel Mintlow, M.D.*, 80 FR 3630, 3652 (2015) (“[S]ufficient mitigating evidence” must be presented “to assure the Administrator that [he] can be entrusted with the responsibility carried by such a registration.”); *Cleveland J. Enmon Jr., M.D.*, 77 FR 57,116, 57,126 (2012) (same); *Robert M. Golden, M.D.*, 61 FR 24,808, 24,812 (1996) (same). Further, past performance is the best predictor of future performance and, when an applicant has “failed to comply with its responsibilities in the past, it makes sense for the agency to consider whether the pharmacy will change its behavior in the future.” *Pharmacy Doctors Enterprises, Inc. v. Drug Enf’t Admin.*, 789 F. App’x at 733 (citing *Jones Total Health Care Pharmacy, LLC v. Drug Enf’t Admin.*, 881 F.3d at 831 (citing *MacKay v. Drug Enf’t Admin.*, 664 F.3d at 820



(“[T]hat consideration is vital to whether continued registration is in the public interest.”) and *Alra Labs., Inc. v. Drug Enf’t Admin.*, 54 F.3d 450, 452 (7th Cir. 1995) (“An agency rationally may conclude that past performance is the best predictor of future performance.”))).

Additionally, in evaluating whether a practitioner should be entrusted with a registration, the Agency considers whether the practitioner has accepted responsibility for any misconduct; circuit courts have approved the Agency’s acceptance of responsibility requirement. *Pharmacy Doctors Enterprises, Inc. v. Drug Enf’t Admin.*, 789 F. App’x at 732; *Jones Total Health Care Pharmacy, LLC v. Drug Enf’t Admin.*, 881 F.3d at 830 (citing *MacKay v. Drug Enf’t Admin.*, 664 F.3d at 820 (“The DEA may properly consider whether a physician admits fault in determining if the physician’s registration should be revoked.”)); *see also Jeffrey Stein, M.D.*, 84 FR 46,968, 46,972-73 (2019) (unequivocal acceptance of responsibility); *Jayam Krishna-Iyer, M.D.*, 74 FR 459, 463 (2009) (collecting cases).

The Agency also has decided that the egregiousness and extent of the misconduct are significant factors in determining the appropriate sanction. *Garrett Howard Smith, M.D.*, 83 FR 18,882, 18,910 (2018) (collecting cases); *Samuel Mintlow, M.D.*, 80 FR at 3652 (“Obviously, the egregiousness and extent of a registrant’s misconduct are significant factors in determining the appropriate sanction.”). The Agency has also considered the need to deter similar acts by Applicant and by the community of registrants and potential registrants. *Id.*

In terms of egregiousness, the violations that the record evidence shows Applicant committed go to the heart of the CSA – not complying with required controlled substance recordkeeping and submitting a registration application that includes a material falsification.

Applicant did not take responsibility for the founded violations. Accordingly, it is not reasonable to believe that Applicant’s future controlled substance dispensing will comply with legal requirements.<sup>2</sup>

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<sup>2</sup> I do not consider remedial measures when an applicant does not unequivocally accept responsibility. In this matter, Applicant did not accept responsibility or propose remedial measures.

For all of these reasons, I find that it would be inconsistent with the public interest for me to entrust Applicant with a registration. Accordingly, I shall order the denial of Applicant's registration application, Control No. W20008908A.

### **ORDER**

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f), I hereby deny the registration application submitted by Crosby Pharmacy and Wellness, Control No. W20008908A, seeking registration in Texas as a practitioner, and I hereby deny any other pending application submitted by Crosby Pharmacy and Wellness for a DEA registration in the State of Texas. This Order is effective [INSERT DATE 30 DAYS FROM THE DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**Anne Milgram,**  
*Administrator.*

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